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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,740	11/23/2007	Ralph A. Cowden III	4396-060415	6915

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EXAMINER	
MILLIGAN, ADAM C	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
07/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/571,740	COWDEN III ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9, in the reply filed on 6/7/2009 is acknowledged. The traversal is on the grounds that the cited prior art teaches EDTA only in combination with cystine and that further limitations of claim 1 are not anticipated or rendered obvious by the cited prior art. These arguments are not found persuasive.

First, because there is no common transitional phrase is present in instant claim 1, the scope of the claim is unclear. In accordance with MPEP 2111.03, examiner interpreted the scope of the claim in light of the specification. Because the specification teaches that ingredients other than EDTA (e.g. Vitamin C) may be present in certain embodiments, the transitional phrase “in which” is interpreted as open.

Second, it is not necessary to anticipate or render obvious claim 1 in order to break unity. Here, the common technical feature is a soluble EDTA pharmaceutical dosage. The prior art cited in the restriction requirement dated 5/12/2009 teaches a therapeutic dosage of EDTA (See Kindness, Claim 1). Given that the common technical feature was known in the prior art, the common technical feature does not rise to the level of a special technical feature. Therefore, lack of unity was properly established.

Claim 10 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objection

Claim 1 objected to because of the following informalities: the phrase "at least every five out of seven days" is unclear as to what time period is being claimed. Examiner suggests "at least five out of every seven days".

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997, The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156).

Rozema teaches EDTA is used to treat a variety of conditions including coronary, cerebral, and peripheral arteriovascular disease (p. 9, 1st para.). EDTA may be administered orally, but has a tendency to bind with nutritional trace elements in the gut

(p.16, 4th full para.). Dosages of EDTA are recommended at 50 mg/kg/day (p.19, 1st full para.), but effects of EDTA have been noticed from dosages as low as 200 mg daily (p.33, last para). Vitamin C is often administered with EDTA in order to help make the carrier solution iso-osmolar and because Vitamin C is a weak chelating agent and is synergistic with EDTA (p.41, Ascorbate). Vitamin supplementation is generally proscribed for all patients taking EDTA (p.22, 3rd full para). Mineral supplementation, including phosphatidyl lipids such as lecithin with phosphytidylcholine, should also be considered for patients being administered EDTA (p.74, Appendix IV).

Rozema does not teach a mouth rinse.

Kotilainen teaches a mouthwash solution which prevents the darkening of dental surfaces and prevents allergic reactions started by heavy metals in the oral cavity (Col. 2, Lines 18-22). Allergic reactions can occur from exposure to the heavy metal ions from dental fillings and prostheses (Col. 1, Lines 15-36). A mouthwash having a complex former with a broad range such as EDTA in order to chelate with, and remove, a wide variety of heavy metal ions (Col. 3, Lines 23-30). The solution is used twice daily (Col. 4, Lines 58-60).

Kotilainen does not teach EDTA administered with an enteric coating.

It would have been obvious to one of ordinary skill in the art, that where heavy metals are released in the mouth due to fillings, the heavy metals may progress through the digestive tract. Thus, treatment for heavy metals in both the mouth and digestive tract would be beneficial in order to fully remove the heavy metals from the body. It

would be further obvious to enterically coat EDTA in order to provide additional protection to the gut.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156) and Rabussay (U.S. 4,355,022).

The combination of Rozema and Kotilainen is discussed above.

The combination does not teach a mouth rinse containing lysozyme.

Rabussay teaches lysozyme dissolved into a mouthwash (Col. 4, Example 1). Lysozyme is an active substance which will attack and cariogenic bacteria in the oral cavity (Col. 3, Lines 31-42).

Rabussay does not teach a mouth rinse comprising EDTA.

It would have been obvious to one of ordinary skill in the art to incorporate lysozyme into the mouth rinse made obvious by Rozema and Kotilainen in order to provide oral antibacterial effects in addition to the heavy metal protection, thereby reducing the chances of deterioration of the already present fillings.

Claim 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents

for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156) and Hsia (U.S. 6,180,139).

The combination of Rozema and Kotilainen is discussed above.

The combination does not teach the administration of lecithin.

Hsia teaches that lecithin supplements are ingested to reduce triglycerides and serum cholesterol (Col. 3, Lines 43-60). After broken down in the body, a product of lecithin called acetyl choline is used in neurological activity including brain and muscle function (Id). Lecithin has also been examined as a possible treatment agent for wide variety of conditions ranging from alcoholism to radiation and toxic chemical exposure (Id). Lecithin is preferably administered orally (Col. 4, Lines 6-7). In Hsai, a phosphatidyl lipid dosage of 20 g was administered twice daily for 12 weeks to subjects having nonalcoholic steatohepatitis. Steatohepatitis has been theorized to be caused by synthesis or secretion of LDL cholesterol (Col. 1, Lines 43-50). All subjects showed statistically significant decrease in hepatic steatosis (Col. 6, Lines 44-49).

Hsia does not teach a supplement having EDTA.

It would have been obvious to incorporate lecithin into the heavy metal neutralizing composition made obvious by Rozema and Kotilainen, given the ability of lecithin to increase neurologic activity and brain function, where heavy metals result in decreased neurological activity.

Further it would be prima facie obvious to optimize the amount of lecithin. See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). One of ordinary skill would recognize that long-term administration of lecithin to healthy volunteers in order to

maintain health and prevent increased cholesterol would require less lecithin than a 12 week regimen for treating a subject having serious liver problems which may be the result of high cholesterol.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156), Hsia (U.S. 6,180,139), and Hermann (Enantioselective pharmacokinetics and bioavailability of different racemic α-lipoic acid formulations in healthy volunteers, European Journal of Pharmaceutical Sciences. Vol. 4, pp. 167-174, 1996).

The combination of Rozema, Kotilainen, and Hsia is discussed above.

The combination does not teach the administration of α-lipoic acid

Hermann teaches the administration of 200 mg per day of α-lipoic acid to healthy human subjects (§ 2.2, 3rd para.). α-lipoic acid is known for a variety of health effects including reduction of oxidative stress, improved insulin simulated glucose disposal, protection against protein glycation, and metal chelating properties (p168, 1st para.). It has been used in the treatment of paresthesias and pain due to diabetic neuropathy.

Hermann does not teach a supplement having EDTA or phosphatidyl lipids.

Because EDTA and α-lipoic acid are both known to chelate with heavy metals and are used for heavy metal detoxification, it would have been prima facie obvious to administer both EDTA and α-lipoic acid for their common function, i.e. heavy metal

detoxification. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156), Hsia (U.S. 6,180,139), Hermann (Enantioselective pharmacokinetics and bioavailability of different racemic α-lipoic acid formulations in healthy volunteers, European Journal of Pharmaceutical Sciences. Vol. 4, pp. 167-174, 1996), and Yasahiro (JP 62012721) (English text summary attached).

The combination of Rozema, Kotilainen, Hsia, and Hermann has been discussed above.

The combination does not teach the incorporation of mushrooms.

The summary of Yasahiro teaches a combination of Shiitake and Reishi mushrooms which exhibit various physiological effects. Among these effects include removal of cholesterol from blood, hypotension, a cardiotonic effect, an analgesic effect, and an immune enhancer.

The summary of Yasahiro does not teach the incorporation of EDTA, α-lipoic acid, or EDTA.

It would have been obvious to combine a treatment for coronary and peripheral arteriovascular disease with ingredients which reduce cholesterol, and provide a

hypotensive and cardiotonic effect in order to improve heart strength and cardiovascular health of a patient who potentially has heavy metal poisoning, thereby increasing the patient's overall health.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612